In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 08-573V
Filed: June 26, 2015
(Not to be published)

TIMOTHY T. BOKMULLER and DEBORAH L. BOKMULLER, as parents of BTB, a minor,	*	
Petitioners,	*	Petitioners' Motion for a Ruling on the Record; Insufficient Proof of Causation; Vaccine Act Entitlement; Denial Without Hearing
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	

John McHugh, New York, NY, for Petitioners.
Ann Martin, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*

This is an action seeking an award under the National Vaccine Injury Compensation Program ("Program")[1] on account of an injury to the Petitioners' son, BTB. For the reasons stated below, I conclude that the Petitioners are not entitled to such an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program ("Program"), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table" ("Table"), originally established by statute at § 300aa-14(a) and later modified, occurred within the applicable time period after vaccination, as prescribed in the Table, then the injury may be *presumed* to qualify for compensation. §§ 300aa-

[1] The applicable statutory provisions governing the National Vaccine Injury Compensation Program are found in 42 U.S.C. § 300aa-10 *et seq*. (2006). Hereinafter, for ease of citation, all "U.S.C." references will be to 42 U.S.C. (2006).

13(a)(1), -11(c)(1)(C)(i), -14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury."

Alternatively, if no Table Injury can be shown, the petitioner may gain an award by instead showing that the vaccine recipient's injury was *actually caused* by the vaccination in question. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii).

Furthermore, "the National Vaccine Injury Compensation Program . . . allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had *significantly aggravated*' a vaccine-related 'illness, disability, injury, or condition.'" *W.C. v. HHS*, 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) (emphasis added) (quoting § 300aa-11(c)(1)(C)). In *Whitecotton v. HHS*, 81 F.3d 1099, 1103 (Fed. Cir. 1996), the United States Court of Appeals for the Federal Circuit stated that "the statutory requirements to make out a *prima facie* significant aggravation claim are analogous to those required to make out a *prima facie* initial onset claim." The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." § 300aa-33(4).

The elements of an off-Table *significant aggravation* case are set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). There, the court combined the test from *Althen v. HHS*, 418 F.3d 1274 (Fed. Cir. 2005), which defines off-Table causation cases, with the test from *Whitecotton*, which concerns on-Table significant aggravation cases. The resultant test has six components:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 ("[T]he *Loving* case provides the correct framework for evaluating off-table significant aggravation claims.").

II

THE OMNIBUS AUTISM PROCEEDING

This case concerning BTB is one of more than 5,400 cases filed under the Program in which it has been alleged that a child's disorder known as an autism spectrum disorder ("ASD"), or a similar disorder, was caused by one or more vaccinations. A brief summary of one aspect of that history is relevant to this Decision.

In anticipation of dealing with such a large group of cases involving a common factual Issue—*i.e.*, whether vaccinations can cause an ASD—the Office of Special Masters ("OSM") devised special procedures. On July 3, 2002, the Chief Special Master, acting on behalf of the

OSM, issued a document entitled the *Autism General Order # 1*,[2] which set up a proceeding known as the "Omnibus Autism Proceeding" ("OAP"). In the OAP, a group of counsel selected from attorneys representing petitioners in the ASD cases, known as the Petitioners' Steering Committee ("PSC"), was charged with obtaining and presenting evidence concerning the general issue of whether those vaccines can cause ASD, and, if so, in what circumstances. The evidence obtained in that general inquiry was to be applied to the individual cases. (*Autism General Order # 1*, 2002 WL 31696785, at *3, 2002 U.S. Claims LEXIS 365, at *8.)

Ultimately, the PSC elected to present two different theories concerning the causation of ASD. The first theory alleged that the *measles* portion of the MMR vaccine can cause an ASD, in situations in which it was alleged that thimerosal-containing vaccines previously weakened an infant's immune system. That theory was presented in three separate Program "test cases," during several weeks of trial in 2007. The second theory alleged that the mercury contained in the thimerosal-containing vaccines can *directly affect* an infant's brain, thereby substantially contributing to the development of an ASD. The second theory was presented in three additional "test cases" during several weeks of trial in 2008.

On February 12, 2009, decisions were issued concerning the three "test cases" pertaining to the PSC's *first* theory. In each of those three decisions, the petitioners' causation theories were rejected. I issued the decision in *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Patricia Campbell-Smith issued the decision in *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Denise Vowell issued the decision in *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Those three decisions were later each affirmed in three different rulings, by three different judges of the United States Court of Federal Claims. *Snyder v. HHS*, 88 Fed. Cl. 706 (2009); *Cedillo v. HHS*, 89 Fed. Cl. 158 (2009); *Hazlehurst v. HHS*, 88 Fed. Cl. 473 (2009). Two of those three rulings were then appealed to the United States Court of Appeals for the Federal Circuit, again resulting in affirmances of the decisions denying the petitioners' claims. *Cedillo v. HHS*, 617 F. 3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, 604 F. 3d 1343 (Fed. Cir. 2010).

On March 12, 2010, the same three special masters issued decisions concerning three separate "test cases" pertaining to the PSC's *second* causation theory. Again, the petitioners' causation theories were rejected in all three cases. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar.12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). None of the petitioners elected to seek review of any of those three decisions.

[2] The *Autism General Order # 1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." An electronic version of that File is maintained on this Court's website. This electronic version contains a "docket sheet" listing all of the items in the File, and also contains the complete text of most of the items in the File, with the exception of a few documents that are withheld from the website due to copyright considerations or due to § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Select the "Vaccine Claims" page, then the "Autism Proceeding" page.

III

PROCEDURAL HISTORY

The *pro se* Petitioners, Timothy and Deborah Bokmuller, filed a Short-Form Autism Petition for Vaccine Compensation on behalf of their son BTB, on August 13, 2008. The case was assigned at that time to Special Master Gary Golkiewicz. Procedings in the case were delayed pending the outcome of the Omnibus Autism Proceeding ("OAP").

On October 12, 2010, Petitioners secured representation by John McHugh. On February 15, 2011, Petitioners filed medical records marked as Exhibits 1-30. Respondent's subsequent "Rule 4 report" noted a lack of required material. (Report, filed Sep. 10, 2008.)

On May 4, 2011, Petitioners filed an Amended Petition alleging that the vaccinations that BTB received throughout his life, specifically including the MMR, Hib, and influenza vaccinations administered on October 25, 2005 as well as the DTP, pneumococcal, and varicella vaccinations of January 27, 2006, possibly caused their son to suffer from acute disseminated encephalomyelitis ("ADEM") or another "underlying condition," making him "unusually susceptible to adverse [vaccine] reactions." A narrative statement by BTB's mother marked as Exhibit 31, along with a letter from Michael Waickman, M.D., marked as Exhibit 32, accompanied the Amended Petition. Dr. Waickman's letter stated that BTB may suffer from ADEM and "vaccine intolerance." (Ex. 32, p. 1.) Dr. Waickman's letter, however, did *not* assert that BTB had any vaccine-caused injury.

On May 9, 2012, the case was reassigned from Special Master Gary Golkiewicz to the undersigned special master.

On May 14, 2012, I filed an Order suspending the time for filing Respondent's supplemental "Rule 4 report" until Petitioners filed an expert report or proposed another way to proceed. Petitioners' expert report deadline was subsequently extended at least ten times between July 13, 2012, and May 26, 2015. (Orders, filed Feb. 6, July 1, Aug. 27, Sep. 16, Oct. 25, and Nov. 14, 2013; Feb. 11, and June 9, 2014; and Jan. 22, and Feb. 25, 2015.) Petitioners were ordered to show cause why their petition should not be dismissed on three occasions when they failed to provide the necessary expert report. (Orders filed Feb. 6, 2013, Sep. 16, 2013, and June 5, 2014.)

On August 5, 2013, Petitioners requested that this case be included with a group of cases known as the "*Mostovoy* Omnibus Group." On February 20, 2015, however, Petitioners filed a Status Report indicating that they no longer wished to be included in the "*Mostovoy* Omnibus Group."

On May 1, 2015, Petitioners filed a Motion for a Decision on the Record as it Stands. In that Motion, they acknowledge that they have been unable to find an expert who could "opine as to the vaccine connection" or "more particularly as to the extent that any damage done by the vaccine was not already in place due to the underlying condition." (Statement, filed May 1, 2015, p. 2.)

IV

FACTS

BTB was born October 18, 2004. (Ex. 3, p. 55.) From birth, the Family Health Center at the Cleveland Clinic's Independence branch ("Cleveland Clinic") provided BTB's primary pediatric care. (Ex. 7, p. 2.)

BTB received the hepatitis B ("Hep B") vaccine on November 2, 2004. (Ex. 5, p. 2; Ex. 7, p. 111.) During his appointment, BTB was also diagnosed as "underweight" and his parents reported a history of "fussiness." (Ex. 7, p. 111.) On November 6, 2004, BTB was treated with silver nitrate for an umbilical cord granuloma, and again his parents complained of fussiness. (Ex. 7, p. 106.) By November 10, 2004, BTB was "eating well" and "sleeping longer." (Ex. 7, p. 104.) Saline drops and a humidifier were recommended to address a complaint of nasal congestion, and a one-week follow-up examination was scheduled. (Ex. 7, p. 104.) On November 15, 2004, BTB was diagnosed with colic. (Ex. 7, p. 103.)

On December 13, 2004, BTB received the recommended two-month vaccinations. (Ex. 5, p. 2; Ex. 7, p. 98) On January 10, 2005, BTB showed signs of a recent upper respiratory infection, but the condition was improving and no orders or prescriptions regarding the infection were issued. (Ex. 7, p. 94.)

On February 11, 2004, BTB received the recommended four-month vaccinations. (Ex. 5, p. 2; Ex. 7, p. 93.) On March 28, 2005, BTB was diagnosed with an upper respiratory infection, after his parents related a three-day history of fussiness and congestion. (Ex. 7, p. 90.)

On April 18, 2005, BTB presented with a rash on his temples and chin, and a history of a ten-day bout of diarrhea that had concluded three days prior. (Ex. 7, p. 87.) He was prescribed hydrocortisone and Nystatin for his rash, and received his scheduled six-month vaccinations. (Ex. 5, p. 2; Ex. 7, p. 89.) On May 9, 2005, he presented with fever, vomiting, and diarrhea, he was diagnosed with a fever, and viral enteritis—inflammation of the small intestines. (Ex. 7, p. 85.)

BTB had an unremarkable well-child visit on July 20, 2005. (Ex. 7, p. 82.) He next visited the pediatrician on August 30, 2005, with nasal congestion and fever, and was diagnosed with a viral throat infection. (Ex. 7, p. 81.)

On October 25, 2005, BTB received the recommended twelve-month vaccinations. (Ex. 5, p. 2; Ex. 7, p. 78.) He presented with a five-day cough and an abated fever thirteen days later on November 7, 2005, and he was diagnosed with "croup"—an upper airway infection with a distinctive cough. (Ex. 7, p. 75.) On November 23, 2005, he again presented with a fever and was diagnosed with pharyngitis. (Ex. 7, p. 72.)

On January 27, 2006, BTB received the recommended fifteen-month vaccinations. (Ex. 5, p. 2; Ex. 7, p. 70.) On February 2, 2006, he was diagnosed with viral enteritis and an upper respiratory infection followed by a middle ear infection and bronchitis two days later. (Ex. 7, pp. 62, 67.)

During a well-child visit on April 15, 2006, BTB's parents reported that they had been reading about autism and expressed concern over BTB's "hand flapping," lack of eye contact,

and poor interaction at day-care. (Ex. 7, p. 61.) A referral was made to Diana Wasserman, M.D., another pediatrician at the Cleveland Clinic, to evaluate his behavior. (Ex. 7, p. 62.) Dr. Wasserman diagnosed BTB as developmentally delayed on April 26, 2006, and on May 3, 2006 as having "pervasive developmental disorder not otherwise specified" ("PDD-NOS"), a form of autism spectrum disorder. (Ex. 7, p. 56, 52-53.) BTB demonstrated a lack of coordination when he was evaluated for occupational therapy at the Cleveland Clinic on June 1, 2006 (Ex. 7, p. 51), and attended therapy on July 10 and 17, 2006 (Ex. 7, pp. 44, 42). On May 1, 2006, BTB was diagnosed with an ear infection.

On May 16, 2006, BTB's parents made an emergency visit to the Southwest General Medical Center in Middleburg Heights, Ohio, due to BTB's excessive vomiting. (Ex. 28, p. 2.) He was prescribed Tylenol and fluids, and was discharged the following day. (Ex. 28, p. 2.) (Ex. 7, p. 54.) BTB's next doctor's visit was on June 27, 2006, with his pediatrician concerning a viral infection and dermatitis. (Ex. 7, p. 48.)

On July 19, 2006, BTB received the Hepatitis A ("Hep A") vaccine. (Ex. 5, p. 2; Ex. 7, p. 42.) On August 12, 2006, he was diagnosed with sinusitis and conjunctivitis. (Ex. 7, p. 41.)

A later medical history taken by Vickie Zurcher, M.D., of the Medical Genetics Clinic, mentions that on or around September, 20, 2006, "Dr. Roizen of the Child Development Center . . . felt [BTB] had autism rather than PDD and [BTB's] parents concur[ed] with this diagnosis."[3] (Ex. 12, pp. 2-3.)

BTB received the influenza vaccine on October 31, 2006. (Ex. 5, p. 2; Ex. 7 p. 38.) On December 12, 2006, he was diagnosed with an upper respiratory infection. (Ex. 7, p. 36.) A diagnosis of croup, cough, and fever followed two days later. (Ex. 7, p. 24-25.) By December 16, 2006, he had also developed an ear infection. (Ex. 7, p. 22.)

BTB received allergy testing at the Cleveland Clinic on February 19, 2007, that confirmed a peanut allergy. (Ex. 7, p. 16.) A year later, on February 21, 2008, tests revealed allergies to peanuts as well as egg-whites, milk, wheat, corn, and soybeans. (Ex. 13, pp. 3-4.)

Teething problems and ear pain resulted in three subsequent pediatrician's visits from May 25, 2007 to August 24, 2007. (Ex. 7, pp. 10, 15, 13.) After a well-visit on November 1, 2007, (Ex. 7, p. 6.), BTB had an upper respiratory infection November 27, 2007, (Ex. 7, p. 4,) and pharyngitis on January 30, 2008. (Ex. 7, p. 2-3.)

On December 30, 2007, BTB was admitted to the Cleveland Clinic's Hillcrest Hospital emergency room for blood in his diaper. (Ex. 10, p. 18.) Multiple small gastric ulcers and one duodenal ulcer were discovered during a colonoscopy performed three days later by Franziska Mohr, M.D., of the Cleveland Clinic. (Ex. 10, p. 29.) Biopsies confirmed inflammation of the stomach lining which was negative for *H. pylori* bacteria. (Ex. 10, p. 35.) The duodenal effects were too nonspecific to attribute to a particular cause. (Ex. 10, p. 35.) A history of gastroesophageal reflux disease ("GERD") was noted, and celiac disease was suspected, as was irritation associated with ibuprofen use. (Ex. 10, p. 30; Ex. 11, p. 37.) By a follow-up visit on February 21, 2008, BTB had completed an eight-week course of Prevacid, and was "doing well

[3] Records from BTB's primary care provider, however, retain the PDD-NOS diagnosis after the September 20, 2006, meeting. In any event, PDD-NOS is considered to be a disorder within the autism spectrum.

from a GI standpoint." (Ex. 11, p. 37.) Genetic tests by Dr. Zurcher on April 8, 2008, further suggested possible celiac disease. (Ex. 12, p. 5.)

A test on May 19, 2008, showed that BTB had abnormally low levels of IgA. (Ex. 15, p. 6.) BTB was examined on June 15, 2008, by Melvin Berger, M.D., of the University Hospitals of Cleveland, Division of Allergy/Immunology. (Ex. 15, p. 5.) A follow-up report dated August 25, 2008, confirmed BTB's IgA deficiency. (Ex. 15, p. 1.) BTB had not, however, "required antibiotics nor had fever once" since his initial visit and the doctor was "pleased" with his progress. (Ex. 15, p. 1.) Immunoglobulin G ("IgG") supplementation was suggested to best avoid fevers either from immunizations or infections while BTB was in school. (Ex. 16, p. 14.)

On February 25, 2009, Felicitas Juguilon, M.D., of the Anti-Aging & Vitality Center in Seven Hills, Ohio, diagnosed BTB with hypogammaglobulinemia. (Ex. 22, p. 8.)

May 7, 2009, BTB received a colonoscopy at Newton Wellesley Hospital in Newton, Pennsylvania, and all observations were reported as normal. (Ex. 23, p. 10.) Biopsies obtained during the procedure suggested possible early inflammatory bowel disease or an allergic/autoimmune process. (Ex. 23, p. 21.) As of September 13, 2010, BTB was doing well receiving acid-reflux treatment and anti-inflammatories, and was having "regular" stools of "normal consistency." (Ex. 23, p. 23.) Addition of a digestive enzyme to his diet was suggested, but no further changes were recommended. (Ex. 23, p. 23.)

V

ISSUES FOR DECISION

Petitioners have sought a Program award, contending that one or more vaccinations[4] injured their son, BTB. In their Motion for a Decision on the Record as it Stands, filed on May 1, 2015, Petitioners assert that BTB has reacted to various vaccinations with episodes of "fever and diarrhea," due to BTB's preexisting condition of "vaccine intolerance" due to a hereditary immune deficiency. (Motion, pp. 1-2.) However, Petitioners in that Motion also acknowledged that they have been unable to find a medical expert willing to opine that BTB has any *vaccine-caused* injury. After careful consideration, I conclude that Petitioners have failed to demonstrate that any of their son's unfortunate episodes of gastrointestinal problems and fevers have been causally connected to any of his vaccinations.

VI

DISCUSSION

To receive compensation under the Program, Petitioners must prove that it is "more probable than not" that either: (1) BTB suffered a "Table Injury"—*i.e.*, an injury falling within the Vaccine Injury Table—corresponding to one of his vaccinations, or (2) BTB suffered an injury that was *actually caused* by a vaccine. *See* §§ 300aa-13(a)(1)(A), -11(c)(1). In my examination of the filed medical records, however, I did not find in the record any evidence that

[4] Petitioners refer both to: (a) "MMR" and "Varicella" in a statement filed on August 5, 2013, and (b) "MMR [], Varicella and Hep A" in a Statement filed on June 5, 2014. BTB received these vaccinations: Oct. 25, 2005 (MMR); Jan. 27, 2006 (Varicella); and July 19, 2006 (Hep A). (Ex. 5, p. 2.)

BTB suffered a "Table Injury." Further, the records do not contain a medical expert's opinion or any other evidence indicating that BTB suffered any injury caused by his vaccinations, or that BTB's autistic spectrum disorder was affected by a vaccine. No physician expressed such an opinion in the records that I reviewed.

Under the statute, a petitioner may not be given a Program award based solely on the petitioner's claims alone. *See, e.g., Taylor v. HHS*, 2012 WL 5205468, at *3 (Fed. Cl. Spec. Mstr. Sept. 14, 2012). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Here, because the medical records do not seem to support the Petitioners' claim, a medical opinion must be offered in support. Petitioners, however, have offered no such opinion.

In this case, Petitioners failed to provide a medical expert's opinion indicating that BTB suffered from an injury that was, more likely than not, caused or aggravated by one or more specific vaccinations. Furthermore, I have reviewed the records and do not find evidence supporting such a claim.

VII

CONCLUSION

I am, of course, sympathetic to the fact that Petitioners' son suffers from a very unfortunate medical condition. However, under the law I can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or competent medical opinion to be vaccine-caused. No such proof exists in the record before me. Accordingly, it is clear from the record in this case that Petitioners have not demonstrated either that a vaccination has "actually caused" any injury to their son, or that any of his symptoms resulted from a vaccine-caused aggravation of his pre-existing genetic immunodeficiency. Therefore, I have no choice but to hereby DENY this claim. In the absence of a timely-filed motion for review of this decision (*See* RCFC app. B), the Clerk shall enter judgment in accord with this decision.

s/George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master